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10/588,323	02/16/2007	Daniel Magilavy	253780	2783

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EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	PAPER NUMBER
1644	
MAIL DATE	DELIVERY MODE
04/08/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,323	MAGILAVY, DANIEL	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/21/2009, 02/12/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 01/05/2009, has been entered.

Claims 1, 6, 23, 26 and 29 have been amended.
It is noted that the proper status identifier for these claims should be (Amended) and not (Original), as currently indicated.

Claims 5 and 30 have been canceled.
It is noted that a canceled claim does not need to be recited.

Claims 1-4 and 6-29 are pending

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Office Action.

This Office Action will be in response to applicant's arguments, filed 01/05/2009.

The rejections of record can be found in the previous Office Action, mailed 10/06/2008.

3. Upon reconsideration of applicant's amended claims, filed 01/05/2009;
the previous objection to the claims have been withdrawn.

4. Upon reconsideration of applicant's amended claims, filed 01/05/2009;
the previous rejections under 35 U.S.C. 112, second paragraph, have been withdrawn.

5. Claim 7 stands rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention

It is apparent that the pSAB152 plasmid is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the the appropriate plasmid. See 37 CFR 1.801-1.809.

In addition to the conditions under the Budapest Treaty, *applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.*

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

Upon reviewing the instant specification, applicant should note that the current ATCC Depository address is as follows:
American Type Culture Collection, 10801 University Boulevard, Manassas, VA 20110-2209.

As noted previously that it was acknowledged that pages 1-2, overlapping paragraph, and pages7-10 of the instant specification appears to rely upon U.S. Patent No. 6,162,432 (1449; #A30) for the deposit of pSAB152 (ATCC 68720),
the record remains not clear whether the conditions for the deposit of biological materials under 35 USC § 112, first paragraph, with respect to the deposit of pSAB152 (ATCC 68720) have been satisfied.

Applicant's Remarks, filed 01/052009, does not address this outstanding rejection.

While applicant filed ATCC deposit information, applicant has not addressed whether *all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.* See MPEP 2410.01 and 37 CFR 1.808.

6. Given the ambiguity concerning the effective priority date of all the instant claims, the prior art rejection under 35 U.S.C. § 102 is applied under 35 U.S.C. § 102(a)(b)(e), as indicated.

7. Claims 1-4 and 6-29 are rejected under 35 U.S.C. § 102 (a)(e) as being anticipated by Vaishnaw et al. (US 200401770635) (see entire document) essentially for the reasons of record.

Applicant's arguments, filed 01/05/2009, have been considered but have not been found convincing essentially for the reasons of record.

Applicant argues the following.

Applicants have amended claim 1 to incorporate the term "wherein the rest period is substantially longer than the interval between administrations." Vaishnaw fails to recite each and every element of the currently rejected claims as required under 35 U.S.C. § 102. Therefore, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-13 and 16-29 as anticipated by Vaishnaw.

While applicant relies upon "wherein the rest period is substantially longer than the interval between administrations",
the claims do not define the "rest period" or "substantially longer".

Therefore, rest period can be any measurable period of time that is "substantially longer than the interval between administrations".

Given the broadest reasonable interpretation of the claims and
given the prior art teachings encompassing multiple treatments via intramuscular and intravenous administration and more particularly the multiple treatments described in paragraphs [0175] - [0181],
the prior art necessarily requires an administration period and a rest period,
wherein the rest period can be "substantially longer than the interval between administrations".

The following is reiterated for applicant's convenience.

Vaishnaw et al. teach the LFA-3 polypeptide of the claimed invention (e.g., see paragraphs [0130] – [0156]) (also see AMEVIVE in paragraph [0203] and plasmid in [0209] 0 [0220],
for the treatment of skin disorders, including psoriasis (e.g. paragraph [0002]- [0005], [0012]-[0014], [0028] [0040] –[0066], [0177]-[0183]
encompassing multiple treatments via intramuscular and intravenous administration (e.g., see paragraphs [0050] – [0058], [0175] - [0181] and
including kits and instructions comprising the LFA-3 polypeptide to treat psoriasis (e.g. paragraphs [0072] and [0196] – [0197].

With respect to the recitation of multiple cycles comprising administration periods and rest periods, including at least 4-8 cycles as well as 8-12 weeks;
the multiple treatments described by the prior art anticipate such claims,
given that multiple treatments necessarily require an administration period and a rest period.

Applicant's arguments have not been found persuasive, given the broadest reasonable interpretation of the claims.

7. Claims 1-4 and 6-29 are rejected under 35 U.S.C. § 102(a)(b)(e) as being anticipated by Dingivan (US2003/0044406)(1449; #A1) (see entire document) essentially for the reasons of record.

Applicant's arguments, filed 01/05/2009, have been considered but have not been found convincing essentially for the reasons of record.

Applicant argues the following.

Like Vaishnaw, Dingivan fails to recite the use of a rest period as identified in the current claims. Therefore, Dingivan also fails to recite each and every element of the currently rejected claims as required under 35 U.S.C. § 102. Accordingly Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-29 as anticipated by Dingivan.

While applicant relies upon "wherein the rest period is substantially longer than the interval between administrations",
the claims do not define the "rest period" or "substantially longer".

Therefore, rest period can be any measurable period of time that is "substantially longer than the interval between administrations".

Given the broadest reasonable interpretation of the claims and
given the prior art teachings encompassing multiple treatments via intramuscular and intravenous administration and more particularly the multiple treatments described in paragraphs [0294]-[0295], [0392], [0395], [0397], [0452], [0454], [0456] and [0459],
in addition to the teachings that the ordinary artisan relied upon the PASI score as a means to assess the severity of psoriasis (e.g., see paragraphs [0028], [0123] – [0125], [0402], [0495], [0554]);
the prior art necessarily requires an administration period and a rest period,
wherein the rest period can be "substantially longer than the interval between administrations".

The following is reiterated for applicant's convenience.

Dingivan teach the treatment of psoriasis (e.g., see paragraphs [0015] – [0022], [0150],
with CD2 antagonists encompassed by the claimed LFA-3 polypeptides alefacept / AMEVIVE (e.g. paragraph 0163]-[0173], [0242]-[0279][00
With multiple dosing (e.g., Summary of the Invention on pages 3-18; Detailed Description, including paragraphs [0139], [0144]-[0145], [[0294]-[0295], [0381]-[0461]),
as well as kits with instructions ([0544] – [0558]).

Note, too, that Dingivan teaches the PASI score as a means to assess the severity of psoriasis (e.g., see paragraph [0028], [0123] – [0125], [0402], [0495], [0554]

With respect to the claimed recitation of multiple cycles comprising administration periods and rest periods, including at least 4-8 cycles, 8-12 weeks and years;
the multiple treatments as described by the prior art anticipate such claims,
given that multiple treatments necessarily require an administration period and a rest period and read on long term treatment to alleviate the severity of the chronic disease of psoriasis.

Applicant's arguments have not been found persuasive, given the broadest reasonable interpretation of the claims.

9. Claims 1-4 and 6-29 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Vaishnaw et al. (US 200401770635) AND Dingivan (US 2003/0044406) (1449; #A1) in view of Magilavy (US 20020009446) (1449; #A3) and as further evidenced by The Merck Manual of Diagnosis and Therapy, Seventeenth Edition (edited by Beers et al., published by Merck Research Laboratories, Whitehouse Station, NJ, 1999; see pages 816-818).

Applicant's arguments, filed 01/05/2009, have been considered but have not been found convincing essentially for the reasons of record.

Applicant argues the following.

Claims 1-30 are rejected under 35 U.S.C. § 103(a) as allegedly obvious over Vaishnaw and Dingivan in view of Magilavy et al. (US 2002-0009446). Again, the Office Action relies on the allegation that "multiple treatments necessarily require an administration and a rest period." As described above, neither Vaishnaw or Dingivan recite a rest period as identified in the current claims. The Office Action does not allege that Magilavy cures this defect, as would be required to make out a prima facie case of obviousness as described in MPEP {} 2142. Because the combination of references fails to recite each and every element of the present claims, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-29 as obvious over Vaishnaw or Dingivan in view of Magilavy.

While applicant relies upon "wherein the rest period is substantially longer than the interval between administrations",
the claims do not define the "rest period" or "substantially longer".

Therefore, rest period can be any measurable period of time that is "substantially longer than the interval between administrations".

Given the broadest reasonable interpretation of the claims and
given the prior art teachings encompassing multiple treatments via intramuscular and intravenous administration and more particularly the multiple treatments described
in paragraphs [0175] - [0181] of Vaishnaw et al. and
in paragraphs [0294]-[0295], [0392], [0395], [0397], [0452], [0454], [0456] and [0459] of Dingivan,
in addition to the teachings that the ordinary artisan relied upon the PASI score as a means to assess the severity of psoriasis (e.g., see paragraphs [0028], [0123] – [0125], [0402], [0495], [0554]) of Dingivan;
the ordinary artisan necessarily would have relied upon an administration period and a rest period,
wherein the rest period can be "substantially longer than the interval between administrations".

In response to applicant's arguments, the following teaching of known practices in the treatment of psoriasis by the ordinary artisan at the time the invention was made has been added.

Coupled with these teachings is the chronic nature of psoriasis itself, where the disease encompasses acute attacks, permanent remission is rare and no therapy is curative (e.g., see The Merck Manual of Diagnosis and Therapy, Seventeenth Edition, edited by Beers et al., published by Merck Research Laboratories, Whitehouse Station, NJ, 1999; see pages 816-818).

As indicated previously to the use of multiple courses of administering LFA-3 polypeptides for a chronic disease such as psoriasis and as would be applicable to the current amended claims, such dosing and modes of administration are result effective variables.

It is well settled that "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980). See also Merck & Co. v. Biocraft Labs. Inc., 874 F.2d 804, 809, 10 USPQ2d 1843, 1847-48 (Fed. Cir. 1989) (determination of suitable dosage amounts in diuretic compositions considered a matter of routine experimentation and therefore obvious).

As dosing and modes of administration are known to the ordinary artisan, it would have been obvious to optimize both the dosing regimens and mode of administration to meet the needs of the patient at the time the invention was made.

Given the clear teachings of the prior art to treat psoriasis with immunosuppressive LFA-3 polypeptides in order to meet the needs of the patients, including teachings of multiple dosing and therapeutic endpoints of reducing the severity of a chronic disease as well as reliance upon criteria such as PSAI scores;
one of ordinary skill in the art at the time the invention was made would have been motivated to administer immunosuppressant LFA-3 polypeptides over long periods of time, including weeks and years, in order to treat a chronic disease such as psoriasis.

The various dosing regimens encompassed by the instant claims were obvious at the time the invention was made, given that it was well known and practice at the time the invention was made to provide immunosuppressive therapy based upon the condition and needs of the patient, as evidenced by the teachings of the prior art.

The following is reiterated herein for applicant's convenience.

Vaishnaw et al. teach the LFA-3 polypeptide (alefacept, AMEVIVE; see entire document) of the claimed invention (e.g., see paragraphs [0130] – [0156]) (also see AMEVIVE in paragraph [0203] and plasmid in [0209] 0 [0220],
for the treatment of skin disorders, including psoriasis (e.g. paragraph [0002]- [0005], [0012]-[0014], [0028] [0040] –[0066], [0177]-[0183]
encompassing multiple treatments via intramuscular and intravenous administration (e.g., see paragraphs [0050] – [0058], [0175] - [0181] and
including kits and instructions comprising the LFA-3 polypeptide to treat psoriasis (e.g. paragraphs [0072] and [0196] – [0197] (see entire document)..

Note that Example 3 of Vaishnaw incorporates PASI improvement in the determination of correlating effective treatment by alefacept / AMEVIVE (e.g., see Example 3 on paragraphs [0203] – [0206]

Similarly to the teachings of Vaishnaw et al.
Dingivan teach the treatment of psoriasis (e.g., see paragraphs [0015] – [0022], [0150],
with CD2 antagonists encompassed by the claimed LFA-3 polypeptides alefacept / AMEVIVE (e.g. paragraph 0163]-[0173], [0242]-[0279]
with multiple dosing (e.g., Summary of the Invention on pages 3-18; Detailed Description on pages 18- , including paragraphs [0139], [0144]-[0145], [[0294]-[0295], [0381]-[0461]),
as well as kits with instructions ([0544] – [0558].
Note, too, that Dingivan teaches the PASI score as a means to assess the severity of psoriasis (e.g., see paragraph [0028], [0123] – [0125], [0402], [0495], [0554]

Magilavy teach the use of the CD2 binding agents of the claimed invention (e.g., LFA3TIP, see pages 20-26 and page 38) for the treatment of inflammatory conditions
that can be administered in dosing and modes of administration that appear to be the same or nearly the same as claimed, such that the dosing and modes of administration are continued until the desired effect is achieved (e.g., see pages 30-33) (see entire document).

Although Magilavy does not disclose psoriasis per se, Magilavy does teach psoriatic arthritis and dermatitis and inflammatory conditions associated with T cells, which is consistent with the inflammatory conditions associated with psoriasis (e.g., see Summary of the Invention on pages 5-6). Note, too, that Magilavy recognizes that PSAI scores as well as nail evaluation are assessed with skin lesions by the dermatologist for efficacy (e.g., see Example V on pages 46-52, including page 50).

With respect to the recitation of multiple cycles comprising administration periods and rest periods and long term treatment,
the multiple treatments described by the prior art render obviousness such claims,
given that multiple treatments necessarily require an administration period and a rest period and are required over a long time in order to alleviate the chronic disease of psoriasis.

As to the use of multiple courses of administering LFA-3 polypeptides for a chronic disease such as psoriasis, such dosing and modes of administration are result effective variables.

It is well settled that "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980). See also Merck & Co. v. Biocraft Labs, Inc., 874 F.2d 804, 809, 10 USPQ2d 1843, 1847-48 (Fed. Cir. 1989) (determination of suitable dosage amounts in diuretic compositions considered a matter of routine experimentation and therefore obvious).

As dosing and modes of administration are known to the ordinary artisan, it would have been obvious to optimize both the dosing regimens and mode of administration to meet the needs of the patient at the time the invention was made.

Given the clear teachings of the prior art to treat psoriasis with immunosuppressive LFA-3 polypeptides in order to meet the needs of the patients, including teachings of multiple dosing and therapeutic endpoints of reducing the severity of a chronic disease as well as reliance upon criteria such as PSAI scores;
one of ordinary skill in the art at the time the invention was made would have been motivated to administer immunosuppressant LFA-3 polypeptides over long periods of time, including weeks and years, in order to treat a chronic disease such as psoriasis.

The various dosing regimens encompassed by the instant claims were obvious at the time the invention was made, given that it was well known and practice at the time the invention was made to provide immunosuppressive therapy based upon the condition and needs of the patient, as evidenced by the teachings of the prior art.

With respect to the kit, the recitation of "a patient who has previously had two cycles of treatment with AMEVIVE" does not patentable weight to the claimed "kit", in the absence of providing some structural distinction over the prior art compositions.
A composition is a composition irrespective of what its intended use is.

From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

"The test of obviousness is not express suggestion of the claimed invention in any or all of the references but rather what the references taken collectively would suggest to those of ordinary skill in the art presumed to be familiar with them." See In re Rosselet, 146 USPQ 183, 186 (CCPA 1965).

"There is no requirement (under 35 USC 103(a)) that the prior art contain an express suggestion to combine known elements to achieve the claimed invention. Rather, the suggestion to combine may come from the prior art, as filtered through the knowledge of one skilled in the art." Motorola, Inc. v. Interdigital Tech. Corp., 43 USPQ2d 1481, 1489 (Fed. Cir. 1997).

An obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of a case. Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. See KSR Int'l Co. v. Teleflex Inc., 82 USPQ2d 1385 (U.S. 2007) ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.").

Given that the prior art goal was to inhibit immune responses in patients with psoriasis with immunosuppressant LFA-3 polypeptides,

incorporating multiple courses of immunosuppressant LFA-3 over a long time would have been routine to the ordinary artisan at the time the invention was made and therefore obvious in designing such methods to effectively treat, manage or ameliorate a chronic disease / condition such as psoriasis.

Applicant's arguments have not been found persuasive.

10. Claims 1-4 and 6-29 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 64-75 of USSN 11/398,908 for the reasons of record.

Applicant's arguments, filed 01/05/2009, have been considered but have not been found convincing essentially for the reasons of record.

Applicant asserts the following.

Applicants respectfully submit that the patent application is in condition for allowance.

In contrast to applicant's assertions, the instant application is not in condition for allowance.

The obviousness-type double patenting rejection is maintained for the reasons of record.

Although the copending claims differ in the targeted diseases, all of the claims rely upon the same AMEVIVE, LFA-3 antagonists to treat inflammatory conditions, including psoriasis in the instant application and psoriatic arthritis and dermatitis in the copending application. Modes of administration and dosing are obvious over one another in that the ordinary artisan would have provided the appropriate effective amounts to achieve therapeutic end results of reducing severity of an inflammatory condition, including the chronic inflammatory conditions encompassed by the claimed methods. Therefore, treating the various inflammatory conditions with the same LFA-3 antagonists would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

11. No claim is allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571) 272-0878.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phillip Gambel/
Primary Examiner
Technology Center 1600
Art Unit 1644
April 6, 2009